

Supporting Statement Part A

Medicaid Drug Rebate Program – Manufacturers: Reconciliation of State Invoice (CMS-304) and Prior Quarter Adjustment Statement (CMS-304a) OMB-0938-0676

The currently approved title for this information collection request is, “Medicaid Drug Rebate Program – Labelers...” This iteration proposes to revise the title to read, “Medicaid Drug Rebate Program – Manufacturers...”

Background

Section 1927 of the Social Security Act (the Act) requires drug manufacturers to enter into and have in effect a rebate agreement with the Federal government for States to receive funding for drugs dispensed to Medicaid recipients. For purposes of this legislation, a drug manufacturer is defined as an entity holding legal title to the National Drug Code (NDC) number for a prescription drug, nonprescription drug or biological product.

To receive a rebate on the drugs dispensed to Medicaid recipients, States are required to submit quarterly utilization data reports to drug manufacturers that have national rebate agreements with the Federal Government. In turn, manufacturers are required to provide rebate payments for covered outpatient drugs as prescribed in section 1927(b) of the Act.

CMS is requesting a three year approval of the manufacturer reporting requirements (forms CMS-304 and CMS-304a) under the drug rebate program. The form CMS-304 (ROSI: Reconciliation of State Invoice) is used by manufacturers to respond to the state’s rebate invoice for current quarter utilization. The form CMS-304a (PQAS: Prior Quarter Adjustment Statement) is required only in those instances where a change to the original rebate data submittal is necessary. There have been no revisions to either of the forms.

A. Justification

1. Need and Legal Basis

Section 1927(a)(1) of the Act requires drug manufacturers to enter into and have in effect a rebate agreement with the Federal Government for States to receive funding for drugs dispensed to Medicaid recipients.

States are required to submit quarterly utilization data reports to CMS and drug manufacturers that have drug rebate agreements with CMS on behalf of the States. In turn, manufacturers are required to provide rebate payments for covered outpatient drugs as prescribed in section 1927(b) of the Act. Copies of these portions of the statute are attached.

2. Information Users

CMS develops the unit rebate amount (URA) from drug pricing information supplied by the drug manufacturers. Each quarter, CMS distributes the URA data to the States. States then report drug utilization data quarterly to the manufacturers (with a copy to CMS), and optionally may associate the URA to that data to establish a payment due amount. Manufacturers, in turn, must remit rebate payments in response to the State's invoice of utilization data.

In response to a need for improved data exchange between manufacturers and States, CMS, in conjunction with outside consultations (see item 8 below), developed the Reconciliation of State Invoice (ROSI), form CMS-304, and the Prior Quarter Adjustment Statement (PQAS), form CMS-304a. The ROSI is to be used by manufacturers to uniformly explain any adjusted rebate payments for the current quarter. It must be used when the manufacturer is not paying the full rebate amount due or the State invoice contains zeros in the unit rebate amount field. The PQAS is used by manufacturers to report adjusted rebate payments only on prior quarter actions/payments. Prior quarter activity includes changes to utilization data submitted by States, revisions to previously disputed units, and prior period adjustments (URA changes). Both forms assist in reducing disputes by standardizing data exchange and improving communication between manufacturers and States.

3. Use of Information Technology

The ROSI and the PQAS may be submitted by manufacturers to States either via paper or electronic media, depending on the needs and capabilities of the manufacturers. Appendix A to forms CMS-304 and 304a is the electronic field size listing which must be used if manufacturers submit these forms to States electronically.

4. Duplication of Efforts

The CMCS is the only CMS component requiring and collecting drug rebate data on the Medicaid program. Therefore, there are no existing data which duplicate these data and could be used in place of drug rebate program data.

5. Small Business

This collection of information does not impact small businesses or other small entities.

6. Less Frequent Collection

Section 1927 of the Act requires manufacturers to pay rebates, including the submittal of any applicable ROSI and/or PQAS forms, within 30 days of receiving State Medicaid drug utilization data. Less frequent reporting of these documents would hamper the efficient administration and function of the Medicaid drug rebate program.

7. Special Circumstances

There are no special circumstances that would require an information collection to be conducted

in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. FR Notice/Outside Consultations

Federal Register Notice

The 60-day notice published in the Federal Register on February 17, 2017 (82 FR 11040). We did not receive any comments.

Outside Consultations

In order to develop a uniform reporting format for current and prior quarter activity which meets the needs of both manufacturers and States, CMS convened an implementation workgroup from June through October of 1995. The workgroup consisted of representatives from the States, drug manufacturers, and CMS. There are no major issues unresolved as a result of this workgroup.

9. Payments or Gifts

There is no provision for any payment or gift to respondents associated with this reporting requirement.

10. Confidentiality

Confidentiality has been assured in accordance with section 1927(b)(3)(D) of the Act.

11. Sensitive Questions

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimate of Burden and Costs to Respondents

Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2016 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

Hourly Wage Estimates

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefit (\$/hr)	Adjusted Hourly Wage (\$/hr)
Accountant / Auditor	13-2011	36.89	36.89	73.78
Business Operations Specialist	13-1000	34.54	34.54	69.08
Computer System Analyst	15-1121	44.05	44.05	88.10
General & Operations Manager	11-1021	58.70	58.70	117.40
Office & Administrative Support Worker	43-9199	17.33	17.33	34.66

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Burden Estimates

(1) CMS-304 – Reconciliation of State Invoice (ROSI)

There are approximately 657 drug manufacturers in the rebate program (derived from the MDR system), of which only about 70% (approximately 460 manufacturers) submit the ROSI to States on a quarterly basis as a result of unit adjustments or disputes. The quarterly burden associated with this package is the time and effort it takes to prepare and submit the Reconciliation of State Invoice (ROSI).

We estimate that it will take an Accountant/Auditor 4 hours at \$73.78/hr, a Business Operations Specialist 20 hours at \$69.08/hr, a Computer Systems Analyst 2 hours at \$88.10/hr, a General Operations Manager 4 hours at \$117.40/hr, and an Office & Administrative Support Worker 40 hours at \$34.66/hr for each manufacturer to complete the quarterly collection/submission for the

ROSI. This equates to a burden of 70 hours per manufacturer per response at a cost of \$3,708.92. In aggregate, we estimate an annual burden of 128,800 hours (460 manufacturers x 70 hr x 4 responses/yr) at a cost of \$6,824,412.80 (\$3,708.92 per response x 4 responses/year x 460 manufacturers).

CMS-304 – State Invoice (ROSI)

Burden Category	Annual Respondents (#of manufacturers)	Annual Responses (frequency)	Annual Responses (total)	Burden per response (hours)	Total Annual Burden (hours)	Hourly labor cost of reporting (\$/hr)	Total Annual Cost (\$)
Data Collection/Submission	460	Quarterly	1,840	70	128,800	Varies	6,824,413

(2) **CMS-304a – Prior Quarter Adjustment Statement (PQAS)**

The PQAS is submitted by the manufacturers on an as-needed basis; however, historically, prior quarter adjustment activity is constant and is typically reported on a quarterly basis by all 657 manufacturers. The quarterly burden associated with this package is the time and effort it takes to generate and submit the Prior Quarter Adjustment Statement (PQAS).

We estimate that it will take an Accountant/Auditor 2 hours at \$73.78/hr, a Business Operations Specialist 5 hours at \$69.08/hr, a Computer Systems Analyst 1 hour at \$88.10/hr, a General Operations Manager 2 hours at \$117.40/hr, and an Office & Administrative Support Worker 18 hours at \$34.66/hr for each manufacturer to complete the quarterly collection/submission for the PQAS. This equates to a burden of 28 hours per manufacturer per response at a cost of \$1,439.74. In aggregate, we estimate an annual burden of 73,584 hours (657 manufacturers x 28 hr x 4 responses/yr) at a cost of \$3,783,636.72 (\$1,439.74 per response x 4 responses/yr x 657 manufacturers).

CMS-304a – Prior Quarter Adjustment Statement (PQAS)

Burden Category	Annual Respondents (#of manufacturers)	Annual Responses (frequency)	Annual Responses (total)	Burden per response (hours)	Total Annual Burden (hours)	Hourly labor cost of reporting (\$/hr)	Total Annual Cost (\$)
Data Collection/Submission	657	Quarterly	2,628	28	73,584	Varies	3,783,637

Summary of Burden Estimates

Form	Annual Respondents (#of manufacturers)	Annual Responses (frequency)	Annual Responses (total)	Burden per response (hours)	Total Annual Burden (hours)	Hourly labor cost of reporting (\$/hr)	Total Annual Cost (\$)
CMS-304	460	Quarterly	1,840	70	128,800	Varies	6,824,413
CMS-304a	657	Quarterly	2,628	28	73,584	Varies	3,783,637
TOTAL	1,117	Quarterly	4,468	98	202,384	Varies	10,608,050

Information Collection Instruments/Instruction/Guidance Documents

- CMS Form 304 - Reconciliation of State Invoice (ROSI)

- In the event that manufacturers disagree with or need to adjust the utilization data submitted by states on the current state invoice, manufacturers are required to complete and submit a ROSI along with their invoice payment.
- Instructions for CMS-304
- Appendix A for CMS 304
 - Provides the electronic field size listing which must be used if manufacturers submit these forms to States electronically.
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- CMS Form 304a – Prior Quarter Adjustment Statement (PQAS)
 - Once the current invoice cycle has passed, manufacturers may discover unit adjustments and/or disputes from a previous quarter. In these instances, manufacturers complete and submit a PQAS as official notification of the discrepancy.
- Instructions for CMS 304a
- Appendix A for CMS 304a
 - Provides the electronic field size listing which must be used if manufacturers submit these forms to States electronically.
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- Appendix C for both CMS 304/304a)
 - Provides the available adjustment and /or dispute codes for the ROSI and /or PQAS.

13. Capital Costs

There are no capital or start-up costs associated with this information collection. The Medicaid drug rebate program has been in existence since January 1, 1991. Manufacturers have had their systems in place for drug rebate data collection since that time.

14. Federal Costs

There is no cost to the Federal Government. The reported information is submitted by manufacturers to States.

15. Changes in Burden and/or Cost Estimates

This package does not propose any program changes. All forms are unchanged.

The total number of annual burden hours increased for both forms due to an increase in the number of respondents (manufacturer participation increased from 610 to 657). The time per response is unchanged. Overall, the burden has increased by 14,504 hours (from 187,880 hr to 202,384 hr).

Cost estimates also increased due to the increase in manufacturer participation, and because the previous PRA package inconsistently reflected cost estimates, and did not designate specific BLS occupational titles and hours to the burden estimates. This iteration proposes to correct those omissions by setting out the time and cost estimates for each of the occupational titles.

Burden Category	Annual Respondents (#of manufacturers)	Annual Responses (frequency)	Annual Responses (total)	Burden per response (hours)	Total Annual Burden (hours)	Hourly labor cost of reporting (\$/hr)	Total Annual Cost (\$)
Currently Approved Burden	427	Quarterly	1,708	70	119,560	15.00	1,793,400
Proposed Burden	460	Quarterly	1,840	70	128,800	Varies*	6,824,413
Adjustment	+33	No change	+132	No change	+9,240	Varies	+5,031,013

*See section 12, above.

CMS-304a – Reconciliation of Prior Quarter Adjustment Statement (PQAS)

Burden Category	Annual Respondents (#of manufacturers)	Annual Responses (frequency)	Annual Responses (total)	Burden per response (hours)	Total Annual Burden (hours)	Hourly labor cost of reporting (\$/hr)	Total Annual Cost (\$)
Currently Approved Burden	610	Quarterly	2,440	28	68,320	15.00	1,024,800
Proposed Burden	657	Quarterly	2,628	28	73,584	Varies*	3,783,637
Adjustment	+47	Quarterly	+188	No change	+5,264	Varies	2,758,837

*See section 12, above.

16. Publication and Tabulation Data

There are no plans to publish this information collection.

17. Display of Expiration Date

The expiration date is set out on the ROSI and the PQAS forms (see respective spreadsheets).

18. Exception to Certification Statement

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

There are no statistical survey methodologies employed with this data collection.